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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,137	01/19/2005	Kenichi Yamashita	2005_0047A	2521

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EXAMINER	
POHNERT, STEVEN C	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,137	YAMASHITA ET AL.	
	Examiner	Art Unit	
	Steven C. Pohnert	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/19/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. It is noted that claims 1 and 4 of the instant are identified as,"after amendment." This is an improper identifier, as the claims have not been amended. The claims should be amended to reflect the proper status according to CFR37§1.121.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-3 are indefinite because it lacks a positive active step relating back to the preamble. The preamble recites a method of analyzing for specimen molecules however the last positive active step is drawn to detect and analyze the degree of diffusion. Therefore it is unclear as to whether the method is drawn to analyzing for specimen molecules or detect and analyze the degree of diffusion of the complex formed between the specimen and probe. It is thus unclear if the claims are drawn to analyzing the degree of diffusion or analyzing a specimen.

Claim 4 is indefinite because it lacks a positive active step relating back to the preamble. The preamble recites a method of analysis of a DNA fragment, however the last positive active step is drawn to detect and analyze the degree of diffusion. Therefore it is unclear as to whether the method is drawn to analysis of a DNA fragment or detect and analyze the degree of diffusion.

Claims 1-4 are also indefinite because the claims do not recite the basic steps of the claimed invention in a positive, active fashion (see Ex parte Erlich 3 USPQ2d, 1011). The claim describes a method for analyzing a specimen molecules (claims 1-3) or DNA (claim 4), but the claim fails to recite any actual steps that define the method. The limitation that the procedure "a step to cause flowing, " "a step to selectively promote diffusion ", a step to detect and analyze are not considered to meet the requirement of a positive process step because no guidance is given as to how to cause flowing, promote diffusion, or detect and analyze.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Garman et al (WO2000/22434, published April 20, 2000).

With regards to claim 1, Garman teaches a method for determining the ability of a test compound to bind a ligand or receptor in a microfabricated conduit (see page 4, lines 18-20). Garman teaches introducing a mixture comprising a test compound, a receptor and ligand (see page 4, lines 23-25). Garman further teaches the test molecule or ligand is labeled (see page 4, line 30). The labeled test molecule or ligand is the probe of the instant invention. Garman teaches the presence of the labeled test

molecule or ligand to flow is determined by reference of the diffusion of the test compound, ligand and receptor (see page 4, lines 13-16). Garman teaches there are different inlets for the introduction of each component to the diffusion region (see page 5, line 12-13). Garman teaches there is laminar flow of the ligand and test compound (see page 6, lines 3-5). Garman et al thus teaches a method of analyzing specimen molecules, by causing laminar flow of a solution containing a specimen (receptor) and a solution containing a probe (labeled ligand or test compound), thus mixing the specimen and probe and detecting the presence of the complex formed (receptor/ligand or receptor/test compound) by differences in diffusion.

With regards to claim 2, Garman teaches the use of fluorescently labeled probes (see page 8, lines 28).

With regards to claim 4, Garman teaches this assay can be used for identifying ligands that bind DNA (see page 9, line 3). Garman et al thus teaches a method of analyzing a DNA fragment, by causing laminar flow of a solution containing a specimen (receptor) and a solution containing a probe (labeled ligand or test compound), thus mixing the DNA and probe and detecting the presence of the complex formed (receptor/ligand or receptor/test compound) by differences in diffusion.

6. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolinsky, et al (WO 1994/00598, published January 6, 1994).

With regards to claims 1, 2, and 4, Wolinsky et al teaches a method of analyzing a specimen by detection of DNA sequences by flow cytometry (see abstract). Wolinksy et al teaches a solution containing FITC-tagged oligonucleotide probes was added to

samples in which PCR amplification had been done (see page 12, 1st paragraph). Wolinsky teaches the samples were allowed to hybridize (form a complex) and then analyzed by flow cytomtery (see page 12, 2nd paragraph). Flow cytometry is analysis of a sample in laminar flow through a microflow channel. Wolinsky et al further teaches detection of the complex by excitation of the fluorescent dyes (FITC and propidium iodine (PI)) (see page 13 1st paragraph). Wolinsky thus teaches a method of analyzing a DNA sample (specimen) by causing a solution containing the DNA and a solution containing fluorescent probe to promote diffusion by laminar flow and detect the presence of the specimen molecule by altered diffusion relative to the speciment molecule and probe molecules.

With regards to claim 3, Wolinsky teaches the instrument was calibrated using calibration beads before each assay and a standard curve was produced (see page 13). Wolinsky et al thus analysis of the degree of diffusion was carried out in reference to a calibration curve.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1and 4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1 and 3 of copending Application No. 10/527,987. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are coextensive in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is drawn to a method for analyzing specimen molecules which comprises: a step to cause flowing of a solution containing the specimen molecules and a solution containing probe molecules capable of forming a complex with the specimen molecules in a micro flow channel in such a fashion that a laminar flow is formed; a step to selectively promote diffusion of the complex formed according to the affinity in the laminar flow, and a step to detect and analyze the degree of diffusion of the complex formed between the specimen molecules and the probe molecules.. Claim 1 of '987 teaches a carrying out a reaction by utilizing a micro flow channel characterized in that, in carrying out a chemical reaction of two kinds or more of reactants capable of reacting each with the others, molecules of the reactants as carried by a fluid are introduced into a micro flow channel and the chemical reaction is carried out efficiently by utilizing interactions of the micro flow channel to cause changes in the

molecular structure, molecular orientation or distribution of the molecules in the solution. Claim 3 of '987 teaches laminar flow. Claim 1 of instant application is obvious over claims 1 and 3 of '987 as they both require the use of a micro flow channel and the two reactants. The two reactants of claims 1 and 3 of '987 are a specimen and probe, thus the claims are obvious.

Claim 4 of the instant application is drawn to a method for analysis of a DNA fragment which comprises: a step to cause flowing of a solution containing a DNA fragment of a specified sequence as a specimen molecule and a solution containing a probe molecule capable of forming a complex with the specimen molecule in a micro flow channel in such a fashion that a laminar flow is formed; a step to selectively promote diffusion of the complex formed according to affinity in the laminar flow; and a step to detect and analyze the degree of diffusion of the complex formed between the specimen molecule and the probe molecule. Claim 1 of '987 teaches a carrying out a reaction by utilizing a micro flow channel characterized in that, in carrying out a chemical reaction of two kinds or more of reactants capable of reacting each with the others, molecules of the reactants as carried by a fluid are introduced into a micro flow channel and the chemical reaction is carried out efficiently by utilizing interactions of the micro flow channel to cause changes in the molecular structure, molecular orientation or distribution of the molecules in the solution. Claim 3 of '987 teaches laminar flow,. . Claim 4 of instant application is obvious over claim 1 and 3of '987 as they both require the use of a micro flow channel and the two reactants. The two reactants of claims 1

and 3 of '987 broadly encompass a DNA fragment and probe, thus the claims are obvious.

Summary

No claims are allowed.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven C. Pohnert whose telephone number is 571-272-3803. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JEANINE A. GOLDBERG
PRIMARY EXAMINER
8/16/07